

PSJ3

Exhibit 394

Summary of the DEA-HDMA Meeting 4/15/08

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**Summary of the DEA-HDMA Meeting 4/15/08**  
**The HDMA Industry Compliance Guidelines**  
**Not for External Distribution**

**DEA Attendees:** D. Linden Barber, Associate Chief Counsel, Diversion and Regulatory Litigation Section; Gary Boggs, Executive Assistant, Office of the Deputy Assistant Administrator; Mark Caverly, Chief Liaison and Policy Section; Robert C. (Chris) Gleason, Deputy Chief Counsel; Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion

**HDMA Attendees:** Robert Barnett, Richard Cooper, (Williams & Connolly); Anita Ducca, Scott Melville (HDMA); David Durkin (Olsson Frank Weeda Terman Bode Matz)

**Meeting summary:**

Bob Barnett asked all attendees to introduce themselves. Chris Gleason thanked the HDMA contingent for coming to DEA.

Then Bob explained the purpose of the meeting and what we hoped to accomplish. He explained the serious concerns among the HDMA members regarding DEA's recent actions regarding suspicious orders. When HDMA first contacted Williams and Connolly regarding possibly challenging DEA, Bob and Rich Cooper recommended an alternative that was based on his prior experience with other clients in similar positions. He recommended that distributors develop a set of "business practices" of their own, a type of "standard," as a better approach to show to DEA and to the outside world that we intended to be part of the solution rather than the problem. Other points that Bob made were:

- HDMA hopes that DEA would find the guidelines acceptable as a voluntary "consent decree", and that we hoped to "receive some form of Imprimatur from you."
- We understood that DEA would not be able to give a specific response today, but we asked that DEA consider them and get back to us.
- We also did not expect these guidelines to result in weakening DEA's enforcement prerogatives. We understood full well that DEA may still feel that in some cases enforcement action may be necessary even with such guidelines.
- That one purpose of a trade association is to help transmit to its members an Agency's expectations. By putting forth such guidelines to DEA, we could help to facilitate such clarification.
- They've been adopted and approved by HDMA's board. However, we suggest that DEA consider them and get back to us and we were open to DEA's suggestions and questions.
- If DEA accepted these guidelines, we would like to make some form of public statement about them; we were open to doing so either jointly with DEA or separately. We also did not care if DEA took credit for them. From our perspective

the most important point was to have them in place to facilitate a common understanding of expectations.

After Bob's introductory remarks, he turned the meeting over to Rich Cooper. Rich gave a brief introduction from a previous experience he had been involved in where a set of voluntary standards were reviewed by FDA and eventually became a standard practice among the medical research community.

Rich then distributed copies of a set of the guidelines with highlighted key points, and walked the DEA staff through the document. One key point Rich made was that the order in question would be stopped until there was an assessment and found that the order was not "suspicious".

The only question during Rich's explanation came from Mark Caverly. Mark requested clarification of "what is stopped". Did that mean anything "over the threshold" would be stopped or would all of the order be stopped? Rich explained that the guidelines indicated that the entire order of the specific product that triggered the threshold should be held and not released. He also stated that other controlled substances that did not trigger the thresholds and non-controlled substances that were part of the same order could still be released. However, the guidelines expected that the entire order for the drug product in question would be held, even if part of it came in under the threshold.

After Rich described the document, he turned the discussion over to Scott Melville to explain HDMA's plans for moving forward from here. Scott explained our anticipated actions for launching the guidelines, following the description we included in our list. He noted that we have had a lot of experience over the years with actions and education to secure the supply chain from the threat of counterfeit drugs and that our initiative on suspicious would have many similarities.

Scott explained that we intended to make the Industry Compliance Guidelines very public and announce it to the press, and said we were open to doing so jointly or separately with DEA, but that we wanted a broad announcement. He spoke about all our planned actions, and particularly noted:

- We intended to help our members implement the guidelines by making consultants known to them that could aid in implementation,
- We will discuss, explain and encourage acceptance of the guidelines by other trade associations, including manufacturing and pharmacy groups. Further, we would encourage them to prepare something similar,
- We'll discuss it with the pain Care Forum,
- Work with members of Congress,
- Hold Webinars and Seminars and engage in other broad education efforts for our members and customers.
- We also anticipated looking at the development of continuing pharmacy education so that pharmacists would have a basis of understanding what efforts they might make to help avoid similar problems.

After Scott's discussion, Chris Gleason thanked us for our efforts, and noted (in an encouraging fashion) that DEA welcomed this dialogue, and recognized the need for cooperative efforts. He noted that DEA sometimes hesitates [to acknowledge or "approve" such documents] given the tendency for the rapid change in the drug trade. DEA sometimes needs the flexibility to change strategies when something comes along that requires a different approach than what might be contained in such a guideline. Bob responded that we attempted to build flexibility into the guidelines to accommodate such changes.

Scott noted that it was also important, however, for our members to obtain clarity regarding DEA's expectations. Our members distribute 7-9 million drug products daily and that with such a high volume of products needed for patient care, it was important to minimize uncertainties. He commented that wholesale distributors can't be involved in the practice of medicine, since we are not the practitioners. However, there are other things we can do to help seek solutions to the problem.

Chris thanked us again and said that he thought we should stay in contact and meet again after DEA had a chance to review the document more closely. He stated he thought we could follow-up "in about a month."

[Subsequent to the meeting, Bob Barnett indicated he would contact Chris in about a week to follow-up.]

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